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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
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| 09/646,204 | 12/21/2000 | Helena Seppanen | 09910-007001 | 5981 |

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EXAMINER

DO, PENSEE T

| ART UNIT | PAPER NUMBER |
|----------|--------------|
| 1641 | 6 |

DATE MAILED: 10/03/2002

Please find below and/or attached an Office communication concerning this application or proceeding.

| Office Action Summary | Application No. | Applicant(s) |
|------------------------------|------------------------|---------------------|
| | 09/646,204 | SEPPANEN ET AL. |
| Examiner | Art Unit | |
| Pensee T. Do | 1641 | |

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1) Responsive to communication(s) filed on 12 December 2000.

2a) This action is **FINAL**. 2b) This action is non-final.

3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4) Claim(s) 1-14 is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5) Claim(s) _____ is/are allowed.

6) Claim(s) 1-14 is/are rejected.

7) Claim(s) _____ is/are objected to.

8) Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9) The specification is objected to by the Examiner.

10) The drawing(s) filed on _____ is/are: a) accepted or b) objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11) The proposed drawing correction filed on _____ is: a) approved b) disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12) The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a) All b) Some * c) None of:

1. Certified copies of the priority documents have been received.
2. Certified copies of the priority documents have been received in Application No. _____.
3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

14) Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).

a) The translation of the foreign language provisional application has been received.

15) Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1) Notice of References Cited (PTO-892) 4) Interview Summary (PTO-413) Paper No(s). _____
2) Notice of Draftsperson's Patent Drawing Review (PTO-948) 5) Notice of Informal Patent Application (PTO-152)
3) Information Disclosure Statement(s) (PTO-1449) Paper No(s). 3 6) Other: _____

DETAILED ACTION

Specification

The disclosure is objected to because of the following informalities: every page including the claim pages of the specification of the present invention has whole punched through the first line. A new submission of the pages of the specification with proper format is requested.

Claim Objections

Claims 1, 10, 11 are objected to because of the following informalities: these claims have missing text because they have hole punched in the first line. Appropriate correction is required.

Claims 11 and 12 are objected to under 37 CFR 1.75(c) as being in improper form because a multiple dependent claim 3, 5, and 7. See MPEP § 608.01(n). Accordingly, the claims not been further treated on the merits.

Amendment Entry

The preliminary amendment filed on 12/21/00 has been acknowledged and entered.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 1-14 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

All the claims lack conventional U.S. claim language such as comprising, having, etc.

In claims 1, 13, 14 please change "characterized in that" to convention claim language such as comprising, having, etc.

In claim 1, line 2, please insert – a—before "material" for correct grammar.

Claim 1, line 11, the phrase "at least on of the mediums" is not understood.

Claim 1 is vague and indefinite of what the magnetic probe-bound particles is being separated from in the second medium, and the third medium?

Claim 1 is unclear of whether the magnetic probe contains a binder that specifically binds to the substance being purified or not?

Claim 3 is vague. The recitation of "such as" is unclear if the detergent is limiting or merely exemplary.

Claims 13 and 14 are unclear of what the magnetic particles are being separated from in the medium.

A broad range or limitation together with a narrow range or limitation that falls within the broad range or limitation (in the same claim) is considered indefinite, since the resulting claim does not clearly set forth the metes and bounds of the patent protection desired. Note the explanation given by the Board of Patent Appeals and Interferences in *Ex parte Wu*, 10 USPQ2d 2031, 2033 (Bd. Pat. App. & Inter. 1989), as to where broad language is followed by "such as" and then narrow language. The Board stated that this can render a claim indefinite by raising a question or doubt as to whether the feature introduced by such language is (a) merely exemplary of the

remainder of the claim, and therefore not required, or (b) a required feature of the claims. Note also, for example, the decisions of *Ex parte Steigewald*, 131 USPQ 74 (Bd. App. 1961); *Ex parte Hall*, 83 USPQ 38 (Bd. App. 1948); and *Ex parte Hasche*, 86 USPQ 481 (Bd. App. 1949). In the present instance, claim 8 recites the broad recitation the concentration of salt is 0.1 to 10 M, and the claim also recites preferably 0.1 to 7M which is the narrower statement of the range/limitation. See also claim 6 for the same issue, e.g. the concentration of protein 0.1-10%, preferably 0.25-5% and most preferably 0.5-2%. See also claim for the same problem. Claims 11 and 12 also have the same problem.

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claim 5 is rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for using protein as a surface tension releasing agent, does not reasonably provide enablement for all the proteins. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the invention commensurate in scope with these claims. The specification fails to teach the use of every protein as a surface tension releasing agent. In fact, the specification does not give any example of using a protein or any protein as a surface tension releasing agent. If one of ordinary skill in the art uses an antibody which is categorized as a protein in the method of the invention and

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the target protein is also an antibody, such antibody would interfere with the binding between the target substance and the magnetic particle.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 1, 2, 7-14 are rejected under 35 U.S.C. 103(a) as being unpatentable over Hawkins (US 5,705,628) further in view of Tuunanen (US 6,448,092).

Hawkins teaches a method of DNA purification and isolation using magnetic particles. The method comprises of incubating single stranded DNA and magnetic particles in a microtiter plate; Add 100 ^{protein} ul of binding buffer (20% PEG 8000 and 2.5 M NaCl) which corresponds to the surface tension releasing agent in the present invention and mix; magnetically separate the particles and remove the DNA to a new microtiter plate. The magnetic particles used were the carboxyl coated magnetic microparticles which were 1 um in diameter. (see col. 9, lines 20-30; example 4).

However, Hawkins fails to teach using a magnetic probe to separate the magnetic particles from the mixture and transferring the magnetic particles to the next medium.

Tuunanen teaches a means for separating magnetic particles and transferring them to a second medium/vessel. The means comprises an elongated protective cover that includes a movable rod comprising a rod magnet in the longitudinal direction of the

cover. The rod magnet consists of a permanent magnet and a ferromagnetic arm which is its extension. The tip of the magnetic rod is pushed into the liquid mixture, magnetic particles adhere to the tip of the magnetic rod; the magnetic rod is removed from the liquid suspension and transferred to a second vessel/medium, the magnet is lifted up to release the adhered particles into the second medium. The magnetic particles are first concentrated at one spot in the vessel from where they are collected by using a magnetic separation means (see 3, lines 28-60).

It would have been obvious to one of ordinary skills in the art to use the magnetic separation device of Tuunanen to separate bound magnetic particles in the method of Hawkins because Hawkins suggests magnetic separation step and transferring the magnetic particles to a second medium/vessel. By using the magnetic separation rod of Tuunanen, the magnetic separation step of Hawkins' method would be carried out at a faster pace thus would save much time and effort and the particles can be transferred to as many vessels as possible. Regarding the concentration the magnetic particles, it would have been obvious to one of ordinary skill in the art to adjust such concentration to execute optimum binding between the magnetic particle and the target analyte.

Claims 1-6, 9, 13, 14 are rejected under 35 U.S.C. 103(a) as being unpatentable over Czerlinski (US 4, 454,234) further in view of Tuunanen (US 6,448,092).

Czerlinski teaches a method for separating magnetic particles. The rabbit anti-BSA antibodies, a given quantity (50 to 100 ul of BSA per 10 ml tube) of BSA-coated magnetic particles are added to a series of tubes. To each tube, a surface tension releasing agent such as a protein of rabbit antiserum diluted in PBS containing 2% (v/v)

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of normal sheep serum and 0.05% Tween 20 is added. The magnetic particles are collected with a magnet, washed with 4 ml of PBS containing 0.05% Tween 20. They are collected and resuspended a total of three times. (see example 3).

However, Czerlinski fails to teach using a magnetic probe to collect the magnetic particles and transfer them to a second medium.

Tuunanen has been discussed above.

It would have been obvious to one of ordinary skills in the art to use the magnetic separation device of Tuunanen for the magnetic separation step in Czerlinski's method because such a device would accelerate the collection of the magnetic particles and thus would accelerate the speed of the separation step so that results would be obtained at a faster rate since the method of Czerlinski requires that the magnetic particles must be collected and resuspended a total of three times.

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Pensee T. Do whose telephone number is 703-308-4398. The examiner can normally be reached on Monday-Friday, 7:00-3:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Long Le can be reached on 703-305-3399. The fax phone numbers for the organization where this application or proceeding is assigned are 703-308-4242 for regular communications and 703-746-5291 for After Final communications.

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Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-0196.

Pensee T. Do
Patent Examiner
September 30, 2002

Christopher L. Chin
CHRISTOPHER L. CHIN
PRIMARY EXAMINER
GROUP 1800-1641
9/1/02